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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,406	04/15/2004	Anton Franz Josef Fliiri	PC9868D	9380

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EXAMINER

BERNHARDT, EMILY B

ART UNIT PAPER NUMBER

1624

DATE MAILED: 07/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/825,406

Applicant(s)

FLIRI ET AL.

Examiner

Emily Bernhardt

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 12,13,15-17,20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11,14,18 and 19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Consistent with earlier parent, which claims 371 priority, restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-11,14,18,19, drawn to compounds,simple compositions and first recited use (psychotic disorders) of formula (I) where $X=N$, $a=1$ and no further fusion exists.

Group II, claim(s) 1,3-7,10-11,14,18,19, drawn to compounds,simple compositions and first recited use (psychotic disorders) of formula (I) where $X=C$, $a=1$ and no further fusion exists.

Group III, claim(s)1-11,14,18,19, drawn to other compounds,etc. not provided by I-II above-eg. where $a=1$ and is further fused or $a=0$ or azaindoles in last 3 species of claim 9.

Group IV, claim(s)10,11,15-17, drawn to additional uses employing compounds of I-III.

Group V, claim(s) 12-13, 20-21, drawn to complex compositions and various uses employing compounds of I-IV along with additional active ingredients, namely various dopamine receptor agonists.

If group III is elected applicants are further required to elect a specific X ring or ring system. If IV is elected a specific class of disorder must be chosen along with a compound group. If V is elected applicants must pick one compound group (i.e. one of I-IV) and a single species from this group and one additional ingredient for a specific use.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I-III relate to compounds of considerable structural dissimilarity in view of the varying X and a choices. The structural feature common to all of the groups cannot be considered a patentable advance over the art given that said feature, namely the 2-indolylmethyl moiety, is old as evidenced by the art applied below.

Group IV is drawn to additional uses. Where more than one use is claimed along with compounds, the first recited invention is considered to form part of the main invention. See 37 CFR 1.475(d). Group V lacks unity with remaining groups as it recites any dopamine receptor agonist which embraces a variety of structurally

unrelated compounds which are not art-recognized equivalents and thus would be expected to raise different issues of patentability within members of the group as well outside the group.

During a telephone conversation with Ms. Konstat on 7/21/04 a provisional election was made with right of traverse to prosecute the invention of I, claims 1-11,14,18 and 19, the same election as in parents. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12,13,15-17,20 and 21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be

rejoined in accordance with the provisions of MPEP 1 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. 1 103(b), 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the

product claims or to otherwise include the limitations of the product claims.

Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C.

121 does not apply where the restriction requirement is withdrawn by the examiner

before the patent issues. See MPEP ' 804.01.

The abstract of the disclosure is objected to because it does not disclose applicants' intended utility. Correction is required. See MPEP ' 608.01(b).

Claims 8,14,18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1.In claim 8 there are 2 different choices recited for R7.

2.In claim 14 "include" implies more than what is positively recited and thus is unclear as to intended scope.

3.Composition claims 18 and 19 are duplicates since the only difference is the recitation of intended uses which is given no material weight in such claims. Note In re Tuominen 213 USPQ 89.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless ☐ ☐

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5,10-11,14,18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Kulagowski (WO'105 cited in applicants' international search report). The WO publication discloses several compounds within the instant scope for the same uses as being claimed herein. See abstract, page 3-9, species on line 31 on p.12 as well as egs. 4,5 and 7.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negated by the manner in which the invention was made.

Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kulagowski. The teachings of Kulagowski as discussed in the above 102 rejection are incorporated herein. Compounds embraced in claims 7-9 require a substituent on the indole ring system such as halo or alkoxy. While compounds pointed out in the above 102 rejection lack this feature, note that the reference teaches in addition to hydrogen the use of halo, alkoxy and other moieties as suitable substituents on the benzene ring. See definitions for R3-R5 on p.4. Species in claim 9 require an additional halo on the phenyl ring which is also particularly preferred by Kulagowski as discussed on p.8 last paragraph. See also p.7 for a list of substituents permitted on R2 rings. Thus it would have been obvious to one skilled in the art at the time the instant invention was made to replace exemplified moieties in the WO publication with those instantly embraced and in so doing obtain instant compounds for use as dopamine antagonists in view of the equivalency teachings outlined above.

Claims 1-11,14,18 and 19 are rejected under judicial doctrine as being drawn to an improper Markush group. The Markush at X and a at the very least embrace more than one invention for the reasons given in the above restriction requirement.

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If nonelected subject matter is to be deleted applicants should check for dependent claims that may no longer be further limiting.

The disclosure is objected to because of the following informalities: Parent history needs to be updated in the application data sheet.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is (571) 272-0664.

If attempts to reach the examiner by phone are unsuccessful, the supervisor for AU 1624, Dr. Mukund Shah, can be reached at (571)272-0674.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.



EMILY BERNHARDT

PRIMARY EXAMINER

Group 1600